

**IN THE UNITED STATES PATENT OFFICE
BEFORE THE BOARD OF APPEALS**

EX PARTE BUSHBY

Application for Patent

Filed on April 2, 2004

Serial Number 10/817,172

For

SYSTEM FOR TREATMENT OF PLANTAR FASCIITIS

Technology Center 3700

APPEAL BRIEF

DONALD P. BUSHBY, APPLICANT

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I. REAL PARTY IN INTEREST

The real party in interest is Donald P. Bushby, the inventor and applicant.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals and/or interferences.

III. STATUS OF THE CLAIMS

Claims 1 – 43 have been canceled.

Claims 44 – 80 have been rejected numerous times. This appeal is being made on the non-final rejection mailed out August 4, 2009. It is noted that the Examiner had indicated allowable subject matter during an interview dated May 8, 2008, however, subsequently continued to reject the claims.

The rejection of Claims 44 – 80 is currently being appealed.

A Request for Pre-Brief Appeal Conference was filed on September 16, 2009. A decision on the Pre-Brief Appeal Conference was mailed out on November 23, 2009 indicating that the Appeal should go forward.

IV. STATUS OF THE AMENDMENTS

An amendment to correct informalities has been filed after the non-final rejection but prior to filing the appeal brief. This amendment corrects several typographical errors, places the claims in better condition for consideration of the appeal and raises no new issues. The clean copy of the claims in the Claims Appendix include the claims prior to this amendment, as it has not yet been entered.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The claims relate generally to an orthotic device (400) that engages the outer skin tissue on the sole of a foot to prevent excessive tensile stress on the plantar fascia. The orthotic device (400) uses a thin flexible stretch-resistant sole member (410) with a strong adhesive layer (410)

so that when the sole member is adhesively applied directly onto the outer skin tissue of the sole, the outer skin tissue is restricted from extending and stretching. This prevents excessive tensile stress on the plantar fascia. (See Paragraphs 0029, 0058)

A) Independent Claim 44

Independent Claim 44 requires an orthotic foot support device (400) that has a thin flexible stretch-resistant sole member (410) of uniform thickness (See Paragraphs 0025, 0029, 0058 – 0060, 0069). This sole member has a shape less than the entire outline of the wearer's foot (See Fig. 4). An adhesive layer (411) has sufficient strength to maintain the stretch-resistant sole member to the outer skin tissue of the foot sole so to restrict extension and stretching of the outer skin tissue. The combination of the stretch-resistant sole member and the adhesive cause the tension forces applied to the plantar fascia of the foot to be shared with the outer skin tissue, the adhesive layer and the stretch-resistant layer to prevent excessive tensile stresses on the plantar fascia (See Paragraphs 0029, 0058).

B) Independent Claim 56

Independent Claim 56 is similar to Claim 44 with the added limitations of a thin flexible strap or tab (420) which is connected to the sole member and extends over the top of the foot to adhesively engage the sides and top of the foot along with the sole member (See Figures 3 and 4). This additional strap and adhesive add additional support for securing the stretch-resistant sole member to the outer skin tissue and for restricting extension and stretching of the outer skin tissue.

C) Independent Claim 60

Independent Claim 60 is similar to Claim 44 with the added limitations of a separate arch strap (420) that engages over the top of the arch of the foot to the sole member to adhesively engage the sides and top of the foot along with the sole member (See Figures 3 and 4). Protective covers 416 cover the adhesive on the sole member and the arch straps until they are secured to the foot.

D) Independent Claim 62

Independent Claim 62 is directed to a method for restricting extension and stretching of the plantar fascia by providing a thin flexible device (400) have a stretch-resistant sole member (410) that excludes the region under the four small toes (See Figures 3 and 4) with a strong adhesive layer (411) to secure the device to the sole of the foot so that the combination of the strong adhesive layer and the stretch-resistant sole member will cause the tension forces applied to the plantar fascia are shared with the device, the outer skin tissue and the adhesive layer to prevent excessive tensile stress on the plantar fascia (See Paragraphs 0029, 0058).

E) Independent Claim 70

Independent Claim 70 is directed broadly to an orthotic foot support device (400) for reducing stress on the plantar fascia of a wearer's foot by the combination of a stretch-resistant sole support (410) and an adhesive layer (411) that secures the stretch-resistant sole support to the sole of a foot so that the sole support absorbs the tensile stress preventing extension and stretching of tissue to prevent excessive tensile stress in the plantar fascia. (See Paragraphs 0029, 0058)

F) Independent Claim 75

Independent Claim 75 is similar to claim 70 with the added limitations of the sole member covering only a portion of the foot and of the elimination of a resilient cushion layer (See Paragraph 0069, discussion of very thin layer) and the added limitation of the sole support having a ratio of elongation to tensile strength that is less than .9 (See Paragraph 0059).

G) Independent Claim 78

Independent Claim 78 is directed to a plantar fascia support device that has a sole support that only partly covers the sole (See Figures 3 and 4) and a ratio of elongation to tensile strength that is less than 0.9 (See Paragraph 0059) along with an adhesive layer (411) to secure the sole support to the outer skin of a sole (See Paragraphs 0029, 0058).

VI. GROUNDS OF THE REJECTIONS TO BE REVIEWED ON APPEAL

1. Whether Claims 45, 47, 61, 67, 69, 72, 77, 78 and 79 are unpatentable under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which applicant regards as the invention.

2. Whether Claims 44, 55, 62, 66 and 70-71 are unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden.

3. Whether Claims 48 – 54 and 56-60, 62-66 are unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden and in further view of Domenico.

4. Whether Claims 45, 72, 75-76, 78 and 80 are unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden and in further view of Desnoyers.

5. Whether Claim 46 is unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden and in further view of Desnoyers.

6. Whether Claims 47, 61, 67 and 69 are unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden and in further view of Huddleston et al.

7. Whether Claim 68 is unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden and in further view of Huddleston et al.

8. Whether Claim 73 – 74 are unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden and in further view of Desnoyers.

9. Whether Claims 77 and 79 are unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden and in further view of Desnoyers and in further view of Huddleston et al.

VII. ARGUMENT

1) Whether Claims 45, 47, 61, 67, 69, 72, 77, 78 and 79 were rejected under 35. U.S.C. 112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which applicant regards as the invention.

Statement of Law

Under the written description of requirement of 35 USC §112, the disclosure of the application relied upon must reasonably convey to the artisan that, as of the filing date of the application, the inventor had possession of the later claimed subject matter. *Vas-Cath Inc. v. Marhukar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). Definiteness is analyzed “not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.” *In re Moore*, 439 F.2d 1232, 1235 (CCPA 1971). The Examiner bears the initial burden of establishing a prima facie case of indefiniteness under 35 USC §112, second paragraph. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability.”)

Examiner's Attempt at Prima Facie Case

The Examiner's basis for this rejection are:

“These claims 45, 47, 61 recite limitations of a ratio of elongation to tensile strength is less than 0.9 and exhibits 15% elongation when subjected to a tensile load approximately equivalent to 25 pounds/inch are not clear to one having ordinary skill in the art from the disclosure of originally filed specification that how applicant has concluded the specifics of these limitations, there are no examples to show the finding and what is elongation at different tensile load of for examples 2, 5, 10, 15, 20 30, 35 and so on. The examiner can best understood by the claim recited limitations of approximately equivalent to 25 pounds/inch, that these findings are not clear. Further, with the limitations of ratio of elongation, how applicant is determined the ratio of elongation of less than 0.9,

whether it is linear ratio? Was it determined up to tear or breaking point of material? How is it determined? There is no substantially data or examples to support the finding of these specific claim limitations.”

Claims 45, 72¹ and 78 have the limitation of:

“said sole member has a ratio of elongation to tensile strength (lb/in-width) that is less than 0.9 to provide a balanced combination of strength and resistance to elongation.” This limitation has direct support in the originally filed specification at paragraph 0059 (emphasis added).

[0059] Thus, a stretch resistant plantar fascia support system using a substantially stretch resistant material may be conveniently and easily applied to the foot of a patient by the patient for the treatment of plantar fasciitis. *For example, the entire foot sole support, or portions of the foot sole support, of the stretch resistant plantar fascia support system may be made of a flexible material that exhibits less than 15 percent elongation when subjected to a 25 lb tensile load under test conditions specified in ASTM D3759.* In addition, *a material with a ratio of elongation to tensile strength (lb/in-width) that is less than 0.9 may be used to provide a balanced combination of strength and resistance to elongation.*

As can be clearly seen in that paragraph, the claimed limitation for the ratio of elongation to tensile strength (lb/in-width) that is less than 0.9 is described in the specification so that one skilled in the art would understand that when considering the materials for the sole member, simply go to any materials handbook or materials data sheet for that material, take the elongation property for that material, divide that number by the tensile strength and make sure the resulting number is less than .9. Or one skilled in the art would simply take the tensile strength, multiply it by .9 and make sure that the elongation is less than that result. If that information was unavailable, then one skilled in the art would simply use the disclosed ASTM D3759² test as set forth in the specification to determine the values for a particular material to determine the ratio. The ASTM D3759 Standard Test Method is the engineering standard for determining the tensile strength and elongation of pressure-sensitive tapes and provides exacting and comprehensive

¹ Claim 72 includes a typographical error by including “(%)” that is not supported in the specification. An amendment has been filed prior to the filing of the brief to correct this error, but has not yet been entered by the examiner.

² The entire ASTM D3759 test is available from ASTM online at www.astm.org or from ASTM, 100 Barr Harbor Drive, West Conshohocken, Pennsylvania, USA

standards for such tests. The ASTM D3759 standard defines the scope of the test as: “This test method covers the measurement of tensile strength at break (breaking strength) and stretch properties (elongation) for pressure-sensitive tapes and labels.”

Examples, data, etc. simply are not necessary for one skilled in the art to be able to select a material based on this limitation, nor has the Examiner stated a legal basis for requiring examples, data, etc. The test as described in the specification is straightforward and within the realm of one skilled in the art. In regard to the Examiner's query as to whether or not the test is at the tear or breaking point, one skilled in the art would certainly recognize that those refer to two separate standards. Tensile strength, which is the subject of the claimed limitation, refers to the strength of the material at break. Tear strength, which is a separate standard, refers to the strength of the material during a tear or rip. One skilled in the art would not be concerned whether or not the test is at tear when measuring for tensile strength. One skilled in the art, particularly when armed with ASTM D3759, would clearly be aware that tensile strength of the material is measured at break. As to whether or not the 0.9 is a linear or nonlinear ratio, it is simply irrelevant. The claimed requirement is only concerned that the ratio of elongation (which is found in most material data sheets for specified materials, or determined under ASTM D3759) to tensile strength (which is also found in most material data sheets for specified materials or determined under ASTM D3759) remains under 0.9. This is a simple arithmetic equation whereby elongation divided tensile strength is less than 0.9, well within the realm of one skilled in the art.

Claims 47, 61, 67, 69, 77, and 79 have the limitation of: “said stretch-resistant sole member exhibits less than 15% elongation when subjected to a tensile load approximately equivalent to 25 pounds/inch in accordance to ASTM D3759.”³

Again, paragraph 0059 of the specification clearly provides support for this limitation. One skilled in the art would certainly be able to access ASTM D3759, conduct a test in accordance with the standards delineated by that standard, and determine whether or not a material would exhibit less than 15% elongation when subjected to a tensile load equivalent to

³ The inclusion of “pounds/inch” is a typographical error. The specification supports the use of “pounds” instead of “pounds/inch”. An amendment has been filed to correct this typographical error prior to filing of the brief, but has not yet been entered by the examiner.

25 pounds in accordance with the conditions of that standard. Examples, data, etc. simply are not necessary for one skilled in the art to be able to select a material based on this limitation. One skilled in the art can easily apply the standards of the test as specified by the ASTM to determine this limitation.

In regard to the examiner's demand for “*there are no examples to show the finding and what is elongation at different tensile load of for examples 2, 5, 10, 15, 20 30, 35 and so on.*”, those are unnecessary. For purposes of the claimed invention, one skilled in the art would not be concerned with different tensile loads at 2, 5, 10, etc. The claimed limitation is that under a 25 pound load, the stretch-resistant sole member exhibits less than 15% elongation. Why is it necessary to show the elongation at 2 pounds, 5 pounds etc.? Additionally, ASTM D3759 will most definitely provide the guidance for conducting the test, as one skilled in the art would certainly be able to utilize. No examples would be necessary for one skilled in the art to understand this simple limitation.

The examiner has failed to provide a *prima facie* case as to why these two claim limitations of unpatentability based on indefiniteness under 35 USC §112, second paragraph.

2) Whether Claims 44, 55, 62, 66 and 70-71 are unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden. 2.

Rejection under 35 USC 103

Statement of Law

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, and (3) the level of skill in the art. *Graham v. John Deer Co.*, 383 U.S. 1, 17 – 18 (1966). “The combination of familiar elements according to known methods is likely to be obvious when it does not more than yield predictable results.” *KSR Int'l Co. V. Teleflex, Inc.*, 550 U.S. 398, 416 (2007). “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* Quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

Cited References

U.S. Patent No. 6,640,465, hereinafter “Burgess” discloses a Disposable Foot Protector to protect the foot from contact with surfaces of indeterminate cleanliness and temperature fluctuations.⁴

U.S. Published Patent Application 2004/0006814, hereinafter “Holden” discloses a Protective Attachment to protect the bottom of the foot from rough terrain, hot sands and pavement without wearing a shoe sandal or otherwise having interfering ties or straps that go between the toes or over the foot.⁵

U.S. Patent No. 3,584,622, hereinafter “Domenico” discloses an ankle support that avoids restriction of desired foot movement.⁶

U.S. Patent No. 3,482,683, hereinafter “Desnoyers discloses a pressure sensitive bundling tape for use in bundling and strapping objects.⁷

U.S. Patent No. 4,997,709, hereinafter “Huddleston et al.” discloses a metal tape for use in repairing rigid fiberglass air ducts.⁸

Examiner's Reasoning for Obviousness

The examiner's basis for the rejection of these claims was:

“Burgess discloses an orthotic plantar fascia device for providing support to and reducing stress on, the plantar fascia of a human foot. The device comprises a thin, flexible and conformable lining; with respect to the limitation of “stretch resistant” Burgess’ device (110) is both flexible and conformable to the foot. The device further includes an adhesive layer (120) on the sole engaging surface for adhering the device directly to the outer skin tissue on the sole of the foot (column 2 lines 62-67) and a protective cover (150) removably disposed over adhesive layer, that when removed, exposes the adhesive layer (column 4 lines 50 – 55). Also Burgess discloses the liner will remain on the foot to allow mobility while still having increased adhesion as a greater effective contact surface area is provided (abstract). Applicant sets forth in the disclosure of the invention that the stretch resistant device” is a sufficiently flexible article with adhesive lining and

⁴ Burgess, Column 2, lines 8 – 10, lines 21 – 23.

⁵ Holden, Paragraphs [0002], [0003].

⁶ Domenico, Abstract

⁷ Desnoyers, Column 1, lines 39 – 42.

⁸ Huddleston et al., Column 1, lines 6 – 12.

that adhesive on the sole of the linings when the lining is on the surface of the foot imparts at least some restriction to extension and stretching of the tissue. The liner of Burgess when applied to the sole of the foot is applied with an adhesive and will provide a prevention and stretch of the tissue, therefore, Burgess's line is equivalent to the claimed support's "stretch resistant" property, since there are no other distinguish structures is required to be stretch less, the device of Burgess meets this claimed limitation. The device has a sole engaging surface (see figure 2), sized and shaped to engage the outer skin tissue on the sole of the foot (column 2 lines 38-40) and extend along the plantar fascia region of the foot from about the ball of the foot to the heel of the foot for providing support to the plantar fascia region of the foot (see fig 2).

Burgess does not disclose that the foot protector can be formed into different sizes or cuts to fit by the wearer. However, Holden teaches a protective attachment that removably attaches to the bottom of the foot (abstract) that is easily trimmed to fit the size and shape of the body part [0003]. At the time of the invention was made, it would have been obvious design choice to one having ordinary skill in the art to form the device of Burgess into different sizes or cuts to fit by the wearer, as taught by Holden to fit various size of feet and to cover whole or partial as user desire."⁹

Claim 44

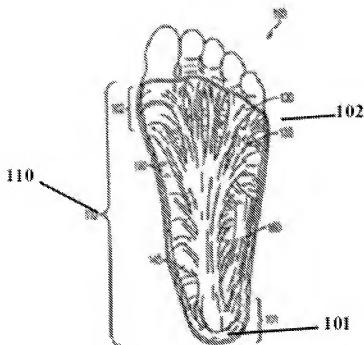
Claim 44 includes the limitations of an *orthotic foot support device* having

- 1) a thin flexible ***stretch-resistant*** sole member of uniform thickness ***having a shape matching less than the entire outline of a sole of a wearer's foot to which the device is to be applied and sized to cover only a portion of the wearer's sole***; and
- 2) an adhesive layer on the sole member for ***securely adhering*** the device directly to an outer skin tissue on the sole of the foot,
- 3) a protective cover removably disposed over said adhesive layer which, when removed, exposes said adhesive layer;
- 4) the ***stretch-resistant sole member sufficiently stretch-resistant to restrict extension and stretching of an outer skin tissue*** on the sole of a foot, when adhered thereto, and
- 5) ***said adhesive layer of sufficient adhesion to maintain the stretch-resistant sole member in adhesive engagement with an outer skin tissue on the sole of the foot, such that tension forces applied to a plantar fascia are shared with an outer skin tissue, the adhesive layer, and the sole member to restrict extension and stretching of an outer***

⁹ Office Action mailed out on August 4, 2009, Section 5, Page 3, 4

skin tissue of a sole of a wearer's foot, whereby preventing excessive tensile stress in a plantar fascia.

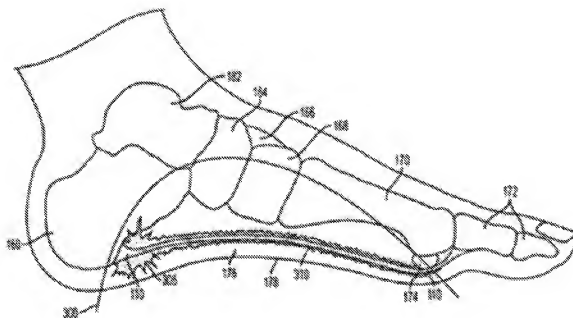
The claimed invention of claim 44 can be easily understood by reference to Figures 1, 2 and 5 of the present application shown below:



As shown in Figure 1, and explained in Paragraph [0003] and [0004] of the present application, the plantar fascia 110 extends across the bottom of the foot from the heel 101 to the ball 102 and spreads out across the width of the foot. As longitudinal and lateral tensile stresses are produced in the bottom of the foot, the plantar fascia 110 absorbs the tensile forces and maintains the shape of the two anatomical arches (longitudinal arch and the transverse arch).

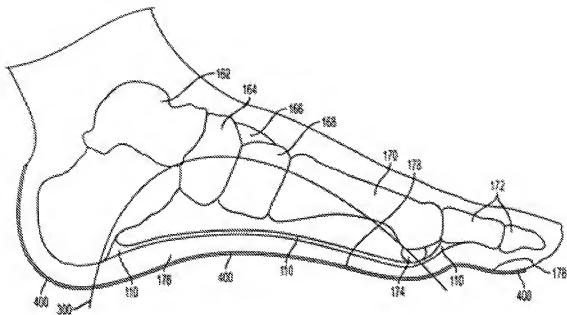
As shown in Figure 2 of the application, illustrated below, the forces that act upon the foot (discussed in Paragraphs [0004], [0005] and [0058] of the application) while standing or in normal motion act in a direction to flatten the arches (formed by the calcaneus 160, the talus 162, navicular 164, cuneiform 166, cuboid 168, and the metatarsals 170 and sesamoid 174). These forces create a stress line represented by line 300 on the foot while in motion. As explained in paragraph [0057] of the application, line 300 is an approximation of the line of forces transferred

through a foot 100 during typical motion, somewhat in the shape of an archer's bow. The plantar fascia 110 extending along near the bottom surface of the foot is analogous to the string under tension in the archer's bow (the line 300). As forces on the arch push the bones downward, spreading the bow out, the pressure on the plantar fascia increases. This pressure creates tensile forces on the plantar fascia which is relatively inelastic, which can lead to tears in the plantar fascia or separate the plantar fascia from bone and other surrounding materials leading to painful inflammation known as plantar fasciitis. (Discussed in Paragraph [0006])



The invention of claim 44 provides an orthotic device to treat this painful condition. The combination of the stretch-resistant layer and the strong adhesive which prevents extending and stretching of the outer skin tissue 176 creates an additional “string” to the archer's bow to share the tensile stresses on the plantar fascia. As shown below, Figure 5 illustrates how the orthotic device 400 of claim 44 with the stretch-resistant layer and the strong adhesive layer engage the outer skin tissue 178. Since the outer skin tissue is constrained from movement by the combination of the stretch-resistant layer and the adhesive, the tensile forces resulting from the pressure on the arch represented by the stress line 300 (the archer's bow), is shared between the

two strings, the plantar fascia 110 and the orthotic device 400.



The differences between the claimed limitations and the disclosure by the references are discussed below to show that the examiner failed to provide articulated reasoning with rational underpinnings to support a legal conclusion of obviousness.

Differences between Burgess and limitations of claim 44

Limitation of Orthotic Device

Claim 44 includes the limitation of an “orthotic device” in the preamble. It is well settled law that “When the limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention.” *Eaton Corp. v. Rockwell Int’l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003). The device, as set forth in claim 44, includes structural limitations that establish its function as an orthotic device. An orthotic device is commonly defined as a device that is used to support, align, prevent or correct the function of movable parts of the body.¹⁰ In claim 44, the structural

¹⁰ Orthotic is commonly defined, such as by Merriam-Webster Dictionary as “(1) of or relating to orthotics; 2) designed for the support of weak or ineffective joints or muscles.” Alternatively, orthotic is commonly defined, such as found on MedicineNet.com in the medical terms dictionary section as “A support, brace or splint used to support, align, prevent or correct the function of movable parts of the body. Shoe inserts are orthotics that intended

limitations of a “foot support device” acting “to restrict extension and stretching of an outer skin tissue of a sole of a wearer’s foot, whereby preventing excessive tensile stress in a plantar fascia” depends on the limitation of an orthotic device for completeness.

An orthotic device has never been defined or used as a protector for protecting the foot from contact with surfaces of indeterminate cleanliness and temperature fluctuations. An orthotic device is not used as a replacement for footwear, but is used in combination with footwear.

The device of Burgess clearly discloses that it is to be used in lieu of ordinary footwear to protect the foot from surfaces of indeterminate cleanliness and temperature fluctuations. It does not disclose, suggest or teach any use as an orthotic device and is incapable of operating as an orthotic device. It fails to support, align, prevent or correct the function of movable parts of the body, but instead merely serves to cushion the sole of the foot and protect the sole from contact with surfaces of indeterminate cleanliness and temperature fluctuations.

The examiner failed to address this limitation in the rejection of this claim, and provided no rationale as to why the disposable foot protector of Burgess is the equivalent of an orthotic device, but merely concludes that the disposable foot protector of Burgess is an orthotic device.

Limitation of Stretch-Resistance

Claim 44 includes the limitation of an orthotic device that has a *stretch-resistant sole member sufficiently stretch-resistant to restrict extension and stretching of an outer skin tissue*.

Burgess discloses the opposite of this limitation in that the disposable foot protector of Burgess is resilient and able to stretch during movement so not limit the movement of the foot. The device of Burgess would not function as intended if it was stretch resistant. “*This is*

to correct an abnormal, or irregular walking pattern, by altering slightly the angles at which the foot strikes a walking or running surface. Other orthotics include neck braces, lumbosacral supports, knee braces and wrist supports”. (See Exhibit A, entered into the record in Applicant’s Response on December 3, 2008).

particularly the case when a fibrous layer is used as the **resilient** sheet member”.¹¹ “Preferably, the fibers are randomly oriented to provide a **good degree of resilience and flexibility**.”¹²

Merriam-Webster defines resilience as: “the capability of a strained body to recover its size and shape after deformation caused especially by compressive stress”. Webster’s New World Collegiate Dictionary defines resilience as: “the ability to bounce or spring back into shape, position, etc.” In order for a body to recover its size and shape after deformation, it must be capable of being deformed and therefore capable of stretching and compressing. Thus, a device that is resilient is not stretch-resistant. Clearly, one skilled in the art would not rationally consider a resilient foot protector capable of adjusting to the flexing of the foot during movement to be a stretch-resistant orthotic device that restricts extension and stretching of an outer skin tissue of a sole of a wearer’s foot to which it is adhered.

Burgess discloses:

“Further, this allows increased mobility as the **foot protector 100 is able to adjust to flexing of the foot during normal walking or running movements without inhibiting foot movement** or causing the tack adhesive to tear away from the foot.”¹³

This does not address the limitation of the orthotic device being stretch resistant. Clearly, Burgess does not disclose the use of a stretch resistant material. Indeed, Burgess disclose just the opposite, a foot protector that can stretch so that it does not inhibit the flexing of the foot during movement.

The examiner stated that “with respect to the limitation of “stretch resistant” Burgess’ device (110) is both flexible and conformable to the foot.”¹⁴ This statement appears to be a *non sequitur*, as it is unclear as how a device that is both flexible and conformable to the foot is somehow stretch-resistant. Flexible is generally defined as being able to be bent repeatedly without injury or damage. Conformable is generally defined as corresponding or consistent in form or nature. Burgess defines the foot protector as conformable because it is flexible to be able to “closely conform to the three-dimensional contours of the sole of the foot.”¹⁵ There is

¹¹ Burgess, column 3, lines 35 – 37.

¹² Burgess, column 4, lines 8 – 10.

¹³ Burgess, column 3, lines 46 – 50.

¹⁴ Office Action, mailed out on August 4, 2009, lines 5-6 of Section 5, Page 3.

¹⁵ Burgess, column 3, lines 35 – 36.

no rational underpinning to conclude that Burgess discloses a stretch-resistant orthotic device that restricts extension and stretching of an outer skin tissue of a sole of a wearer's foot, whereby preventing excessive tensile stress in a plantar fascia, based on the rationale that the prior art device is stretch-resistant since it is both flexible and conforming. This reasoning makes absolutely no sense and certainly falls far short of the requirement under KSR that "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness". The examiner has failed to provide any sort of articulated reasoning with any rational underpinning in this instance.

The examiner later expands this reasoning by stating that *"The liner of Burgess when applied to the sole of the foot is applied with an adhesive and will provide a prevention and stretch of the tissue, therefore, Burgess's liner is equivalent to the claimed support's "stretch resistant" property, since there are no other distinguish structures is required to be stretch less, the device of Burgess meets this claimed limitation."*¹⁶ This reasoning again is unclear. Apparently, the examiner is reasoning that since the Burgess liner is applied with an adhesive, it will not longer be able to stretch and thus meets the requirement in the claim that the sole support member of the orthotic device be formed from a stretch resistant material. The examiner disregards that the liner of the disposable foot protector of Burgess is intended to be resilient, thus deformable and not stretch resistant, and does not restrict the extension and stretching of the outer skin tissue of the foot but instead *"is able to adjust to flexing of the foot during normal walking or running movements without inhibiting foot movement or causing the tack adhesive to tear away from the foot."*¹⁷ The only conceivable manner in which the liner of Burgess would be able to adjust to flexing of the foot during walking or running movements without inhibiting foot movement or causing the tack adhesive to tear away from the foot is for it to stretch, otherwise either the foot movement would be restricted or the tack adhesive would tear away. The liner of the disposable foot protector of Burgess must be able to stretch in order to perform as disclosed, and thus is not stretch-resistant. Common sense dictates that the liner of Burgess is able to stretch in order to adjust to the flexing of the foot during normal walking or running movements without inhibiting foot movement or causing the tack adhesive to tear away from the

¹⁶ Office Action mailed out on August 4, 2009, Section 5, Page 4, lines 1 – 6.

¹⁷ Burgess, column 3, lines 47 – 50.

foot. There is no other rationale available.

The examiner has failed to provide any articulated reasoning with rationale underpinnings to support a legal conclusion of obviousness.

Limitation of Adhesive Strength

The foot protector of Burgess is a resilient sheet member 110 of substantially uniform thickness with a tack adhesive layer. The tack adhesive layer 120 is “*sticky enough to reliably hold the foot protector 100 against the foot 200, but is not so sticky that it causes difficulty or discomfort in removing the foot protector 100 from the sole of the foot 200. The easier it is to remove the foot protector 100 from the sole of the foot 200, the more the wearer can experience the comfort level of a conventional slipper.*”¹⁸

Claim 44 includes the limitation of an adhesive layer that has *sufficient adhesion to maintain the stretch-resistant sole member in adhesive engagement with an outer skin tissue on the sole of the foot, such that tension forces applied to a plantar fascia are shared with an outer skin tissue, the adhesive layer, and the sole member to restrict extension and stretching of an outer skin tissue of a sole of a wearer’s foot, whereby preventing excessive tensile stress in a plantar fascia.*

Burgess discloses the opposite of this limitation as the adhesive strength of the adhesive layer is intended to allow increased mobility of the protector 100 to adjust to flexing of the foot *without inhibiting foot movement.*¹⁹ The orthotic device of claim 44 defines limitations to *restrict extension and stretching of an outer skin tissue* in order to prevent excessive tensile stress in a plantar fascia.

The examiner provides no basis for why this limitation would be obvious in view of Burgess. The closest rationale appears to be that since Burgess discloses using a low tack adhesive, then any adhesive that “*adhesive on the sole of the linings when the lining is on the surface of the foot imparts at least some restriction to extension and stretching of the tissue.*”²⁰ This rationale is not supported by the disclosure of Burgess. Burgess teaches the opposite of this

¹⁸ Burgess, column 3, lines 2 – 8.

¹⁹ Burgess, column 3, lines 46 – 51.

²⁰ Office Action mailed out on August 4, 2009, Section 5, Page 3, last line, Page 4, first line.

rationale, in that Burgess specifically discloses that the adhesive layer and resilient nature of the foot protector will not inhibit movement and flexing of the foot during movement. Burgess further discloses the use of an adhesive of low tack strength so the foot protector is easy to use and will not inhibit the movement of the foot.²¹

The present invention, as presently claimed, is just the opposite, it is intended to inhibit the movement of the foot and the outer skin tissues in order to prevent excessive stress on the plantar fascia. The low tack adhesive of Burgess would not function to do so. Burgess teaches away from using a strong adhesive so that it would not “*causes difficulty or discomfort in removing the foot protector 100 from the sole of the foot 200. The easier it is to remove the foot protector 100 from the sole of the foot 2000, the more the wearer can experience the comfort level of a conventional slipper.*”²² Clearly the outer limit of the adhesive strength is such strength that would reliably hold the foot protector against the foot, but not so strong that would cause any discomfort to the wearer.

The examiner has failed to provide a rational underpinning to conclude that Burgess discloses an equivalent structure to the claimed limitation of an adhesive layer of sufficient adhesion to maintain the stretch-resistant sole member in adhesive engagement with an outer skin tissue on the sole of the foot, such that tension forces applied to a plantar fascia are shared with an outer skin tissue, the adhesive layer, and the sole member to restrict extension and stretching of an outer skin tissue of a sole of a wearer's foot, whereby preventing excessive tensile stress in a plantar fascia. The plantar fascia is essentially inelastic requiring a strong adhesive to share the tensile forces on it and since the tack adhesive of Burgess is intended for temporary light duty use, a strong adhesive would not be desirable, as discussed throughout Burgess. The examiner has failed to provide an articulated reasoning with rational underpinnings as to how a resilient foot protector with a low tack adhesive for use as a “cushioned house slipper” can act as an orthotic device having a stretch-resistant sole support that works with a strong adhesive to restrict the extension and stretching of the outer skin tissue so that the tensile forces on the plantar fascia are shared with the outer skin tissue, the adhesive layer and the stretch-resistant sole member to prevent excessive tensile forces on the plantar

²¹ Burgess, column 3, lines 1 – 8, lines 47 -50.

²² Burgess, column 3, lines 3 – 8.

fascia.

Limitation of Size and Shape

Changes in mere size or shape in some circumstances may be considered obvious combinations or modification, but would not be considered obvious in the case where doing so would destroy the functioning of the reference, or make it unsatisfactory for its intended purpose. “If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” (MPEP 2143.01)

Claim 44 includes the limitation of *“having a shape matching less than the entire outline of a sole of a wearer's foot to which the device is to be applied and sized to cover only a portion of the wearer's sole”*.

The examiner acknowledges that Burgess fails to disclose this limitation. The examiner states that it would be obvious to modify the device of Burgess as taught by Holden which discloses a protective adhesive pad to “form the device of Burgess into different sizes or cuts to fit by the wearer as taught by Holden to fit various size of feet and to cover whole or partial as user desire.” However, to do so would render the prior invention of Burgess unworkable for its intended purpose, that is protect the sole of a foot from environmental conditions.

To modify Burgess as required to meet the limitation of claim 44 would destroy its intended function *“to protect the foot from contact with surfaces of indeterminate cleanliness and temperature fluctuations”*.²³

The examiner has failed to provide a rational underpinning as to why it would be obvious to modify the disposable foot protector of Burgess as suggested when it would render it unworkable in order to meet the claim limitation of *“having a shape matching less than the entire outline of a sole of a wearer's foot to which the device is to be applied and sized to cover only a portion of the wearer's sole”*.

Summary

Claim 44 includes the limitations that Burgess fails to disclose of:

- 1) an orthotic device;

²³ Burgess, column 1, lines 20 - 23

- 2) a stretch-resistant sole member;
- 3) the stretch-resistant sole member having a size and shape less than the entire outline of the wearer's foot;
- 4) an adhesive layer of sufficient adhesion such that the tension forces applied to a plantar fascia are shared with the outer skin tissue, the adhesive layer and the sole member to restrict extension and stretching of an outer skin tissue of a sole of a wearer's foot to prevent excessive tensile stress in the plantar fascia.

The examiner cites references that disclose a disposable foot protector with a flexible resilient sole member covering the entire foot that uses a low tack adhesive so not to restrict the movement of the foot under normal walking and running so the foot protector acts a cushioned house slipper, and a protective pad that partly covers the foot. The examiner failed to provide articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

Claim 55

Claim 55 includes the limitations of an orthotic foot support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as the sole member being formed of a single layer of woven fabric material.

Claim 55 depends from claim 44 and stands with claim 44. Further, claim 55 adds the additional limitation of using a single woven fabric layer. Woven fabric is generally defined as a planar structure produced by interlacing two or more sets of yarns, fibers, rovings, or filaments where the elements pass each other essentially at right angles and one set of elements is parallel to the fabric axis. By their nature of the interlacing of the fibers at right angles, woven fabric layers are stretch-resistant. Burgess on the other hand defines the material for the disposable foot protectors as "Preferably, the fibers are randomly oriented to provide a good degree of resilience and flexibility."²⁴ The random orientation of the fibers of the material of Burgess is intended to provide resilience and flexibility while the orientation of the fibers at right angles to one another with one set of fibers parallel to the axis of the fabric is intended to provide stretch-

²⁴ Burgess, column 4, lines 8 – 10.

resistance. Burgess fails to disclose a woven fabric, and to modify Burgess to use a woven fiber would render the Burgess device unworkable for its intended purpose of resilience and flexibility.

The examiner stated that *“Burgess obviously discloses a single woven fabric layer (as disclosed in column 4 lines 5 - 8 that the it is made of natural fibers, the examiner interprets that the natural fiber is woven fabric layer as required by claim).”*²⁵ The interpretation by the examiner is unreasonable. Natural fibers are not necessarily woven. Woven is a specific term of art requiring that the fibers be interlaced at right angles to one another to provide stretch-resistance. Burgess on the other hand requires that the fibers be randomly oriented in order to provide resilience and flexibility, the opposite of the claimed limitation.

The examiner has failed to provide articulated reasoning with rational underpinnings as why this limitation would be obvious in view of Burgess.

The examiner states that after discussing the woven layer:

“with respect to the limitations of restricting extension and stretching of the outer skin tissue on the sole of the foot”, when the device described above adheres to sole, it will obviously restrict extension of the skin and such that the tension forces applied to the plantar fascia from the forces on an arch of the foot which push the bones of the foot downwardly, and are able to reduce tension in the plantar fascia (0027), when the device of Burgess is secured to the sole of the user’s foot which will result in treating pain in at least one of the heel, or arch or ball of the foot (see paragraph 0016 and 0027) and controls the step to prevent extension and stretching, reduce tension on the plantar fascia of the foot.”²⁶

It is unclear as to what this pertains, and even as to what it means. The Burgess references do not utilize numbered paragraphs, and even if it did, does not mention the plantar fascia or any mention of treating pain. It appears that the examiner is misquoting from the present application to provide the rationale for this rejection in hindsight, but it does not meet the standard of articulated reasoning. This is clearly not any form of articulated reasoning or rational underpinning.

²⁵ Office Action mailed out August 4, 2009, Section 5, page 5, lines 3 – 7.

²⁶ Office Action mailed out August 4, 2009, Section 5, page 5, lines 8 – 16.

Claim 62

Claim 62 is an independent claim that sets forth a method for restricting extension and stretching of the plantar fascia of a human foot, comprising the steps of:

- 1) providing a thin flexible device of substantially uniform thickness having a stretch-resistant sole member sized and shaped to be conformed to an outer skin tissue on at least a portion of a sole of a wearer's foot in a region of the foot from a heel of a foot to a distal end of the toes, excluding the region under the four smaller toes; and
- 2) an adhesive layer on at least a portion of said sole member for adhering said device to the outer skin tissue on the sole of a wearer's foot, said adhesive layer of sufficient adhesive strength to maintain said device in place on the outer skin tissue on the sole of the foot and said stretch-resistant sole engaging surface sufficiently stretch-resistant so as to restrict extension and stretching of the outer skin tissue when adhered thereto;
- 3) adhering said sole member to an outer skin tissue on a portion of a sole of a foot such that tension forces applied to the plantar fascia are shared with said device outer skin tissue, said adhesive layer and said sole member to restrict extension and stretching of an outer skin tissue on a sole of a foot, whereby; preventing excessive stress on a plantar fascia.

Neither the device of Burgess or Holden as discussed above disclose the use of a stretch resistant sole member with an adhesive of sufficient strength to restrict extension and stretching of the outer skin to prevent excessive stress on a plantar fascia. Thus, neither Burgess or Holden provide any steps of adhering a stretch-resistant sole member to the outer skin tissue on the sole of a wearer's foot to restrict extension and stretching of the outer skin tissue to prevent excessive stress on a plantar fascia. There is no rationale presented to conclude that it would be obvious to modify the devices of Burgess or Holden in order to restrict the extension and stretching of the plantar fascia of a human foot by the steps set forth in claim 62.

Additionally, the Burgess reference teaches away from, *“excluding the region under the four smaller toes”* as Burgess is intended to protect the foot from contact with surfaces of indeterminate cleanliness and temperature fluctuations. Burgess states that it may be slightly larger or slightly smaller than the size of the foot, but has an outline generally matching the

shape the foot, thus not excluding any region of the foot from being protected “*from contact with surfaces of indeterminate cleanliness and temperature fluctuations*”. Excluding a region of Burgess would allow contact of the foot to the floor surfaces thus would destroy the functioning of the reference, or make it unsatisfactory for its intended purpose. (MPEP 2143.01)

The examiner has failed to provide articulated reasoning with rational underpinnings as to why the claimed method would be obvious in view of Burgess and Holden.

Claim 66

Claim 66 includes the limitations of claim 62 with the added limitation of “*adhering opposed ends of a thin flexible strap extending laterally outward from opposite sides of said stretch-resistant sole member to the outer skin tissue on a side or a top of a foot to provide a further means for maintaining said sole member in engagement with a sole of a foot; and wherein said device is used for the treatment or prevention of plantar fasciitis*”.

Neither Burgess or Holden, disclose such a limitation nor teach or suggest a reason which would motivate one to add such a feature or step to their devices. Additionally, Holden teaches away from straps “*without wearing a shoe sandal or otherwise having interfering ties or straps that go between the toes or over the foot*”²⁷. Further, the combination of references fails to teach a device “*used for the treatment or prevention of plantar fasciitis*”, thus failing to meet all the limitations of the claim.

The examiner failed to provide any reasoning as to why this claim would be obvious in view of Burgess and Holden. No rationale whatsoever is presented by the examiner under this rejection.

Claim 70

Claim 70 is an independent claim that includes the limitations of an orthotic foot support device for reducing stress on the plantar fascia of a wearer’s foot, said device comprising:

a stretch resistant, uniform thickness sole support, having a shape matching less than an entire outline of a sole of an individual’s foot where the device is to be applied;

²⁷ Holden, column 1, lines 3 – 5 of paragraph [0002].

an adhesive layer on said sole support for attaching said sole support to a sole of the wearer's foot such that said sole support absorbs tensile stress thus preventing extension and stretching of tissue on a bottom of the wearer's foot on which said sole support is attached, whereby preventing excessive tensile stress in a plantar fascia.

As discussed above, neither Burgess or Holden disclose the use of an orthotic device, much less an orthotic foot support device for reducing stress on the plantar fascia of a wearer's foot. This limitation in the preamble is necessary to support the structural limitation of the sole support absorbing tensile stress thus preventing extension and stretching of tissue on a bottom of the wearer's foot on which the sole support is attached to prevent excessive tensile stress in a plantar fascia.

Also, as discussed above, neither Burgess or Holden disclose a stretch resistant layer, instead these references disclose the use of a resilient material that will not restrict movement of the foot. Further, as discussed above, neither Burgess or Holden disclose using an adhesive of sufficient strength for attaching the sole support to a sole of the wearer's foot such that the sole support absorbs tensile stress thus preventing extension and stretching of tissue on a bottom of the wearer's foot on which the sole support is attached, whereby preventing excessive tensile stress in a plantar fascia. Instead, the adhesive of Burgess is intended to allow ease of movement of the foot and to be easily removed. The preferred adhesive of Burgess is that of a low tack adhesive used in Post-It notes.²⁸ The disposable foot protector of Burgess with its resilient cushioned sole member and low tack adhesive would certainly not be capable of preventing excessive tensile stress in a plantar fascia.

Burgess also fails to disclose a sole support member that has a size and shape less than an outline of the wearer's foot. To do so would render the foot protective device of Burgess unusable since the sole purpose of Burgess is to protect the sole of the foot from the environment. "If proposed modification would render the prior art invention being modified

²⁸ See Burgess, column 2, lines 65 – column 3, line 8. "For example, adhesives used in BAND-AIDS.TM., POST-IT NOTES.TM., feminine pads, and the like may be used as the tack adhesive layer 120. Preferably, the tack adhesive used in the tack adhesive layer 120 is sticky enough to reliably hold the foot protector 100 against the foot 200, but is not so sticky that it causes difficulty or discomfort in removing the foot protector 100 from the sole of the foot 200. The easier it is to remove the foot protector 100 from the sole of the foot 200, the more the wearer can experience the comfort level of a conventional slipper."

unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” (MPEP 2143.01)

The examiner has failed to provide articulated reasoning with rational underpinning for the conclusion that the disposable foot protector of Burgess and/or protective attachment pad of Holden would render obvious the claimed invention of an orthotic foot support device reducing stress on the plantar fascia of a wearer’s foot having the limitations of a stretch resistant, uniform thickness sole support, having a shape matching less than an entire outline of a sole of an individual’s foot where the device is to be applied; an adhesive layer on said sole support for attaching said sole support to a sole of the wearer’s foot such that said sole support absorbs tensile stress thus preventing extension and stretching of tissue on a bottom of the wearer’s foot on which said sole support is attached, whereby preventing excessive tensile stress in a plantar fascia.

Claim 71

Claim 71 depends from claim 70 and stands with that claim. It further includes the limitations of a strap that is affixed to the foot transversely to the sole support member. The strap includes adhesives. Protective layers cover the sole support member and strap prior to use.

Neither Burgess or Holden disclose the use of a strap extending transverse to the sole support member. Not only do neither reference disclose the use of a strap, or any reason for adding a strap, but Holden specifically teaches away from the use of a strap. The examiner provided no rationale as why it would be obvious to modify Burgess or Holden to use a strap transverse to the sole support member but merely concluded that it would be obvious to do so. Instead the transverse strap provides the capability of additional securement of the sole member to the outer skin tissue to prevent excessive stresses on the plantar fascia.

The examiner has failed to provide articulated reasoning with rational underpinnings as why this claimed invention would be obvious in view of the combination of Burgess and Holden.

3) Whether Claims 48 – 54 and 56-60, 62-66 are unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden and in further view of Domenico.

Claims 48 - 50

Claims 48 – 50 include the limitations of claim 44 plus the additional limitation of a thin flexible arch strap having opposed ends extending laterally outward from opposite sides of the stretch-resistant sole member with an adhesive layer to adhere to an outer skin tissue on a side or top of an arch of the foot.

The examiner restated the earlier rejection using the combination of Burgess and Holden and further acknowledged that neither Burgess nor Holden disclose thin flexible straps extending laterally outward from the opposite sides of the stretch-resistant sole member to adhere to a side or top of an arch of the foot.²⁹ The examiner cites Domenico as teaching a support device for prevention of ankle injuries having thin flexible straps extending laterally outward from opposite sides to partially encircle the talus, the navicular, the cunifform and the cubiod region of the foot, an arch strap and a heel strap.³⁰ However, Domenico does not disclose any device that would restrict the outer skin tissue along the plantar fascia, and actually discloses the opposite, *“The generally V-shaped opening defined by rear edges of the stirrup portions 22 and an upper edge of the upwardly extending portion 20 prevents restriction of movement of the calf muscle and Achilles’ tendon. Such restriction, if present, would interfere with normal running. Moreover, because the foot receiving member 16 is substantially open at the front, and the forwardly extending portion 18 terminates at about the forward extreme of the metatarsus, the support device 10 does not interfere with plantarflexion or dorsiflexion of the foot.”*³¹

Domenico fails to disclose an orthotic device for treating plantar fascia nor does Domenico disclose an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia. None of the references taken in either singly or in combination with one another would cause one skilled in the art to combine their respective disclosures to provide an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to

²⁹ Office Action mailed out on August 4, 2009, Section 6, page 6, last two lines through line 5 of page 7.

³⁰ Office Action mailed out on August 4, 2009, Section 6, page 7, first full paragraph.

³¹ Domenico, Column 2, lines 31 – 41.

prevent excessive tensile stress in a plantar fascia.

The examiner has failed to provide articulated reasoning with rational underpinnings to support a legal conclusion of obviousness as to why the claimed invention of an orthotic device with a stretch-resistant sole support and straps extending either over the arch, around the heel or over the front of a foot with strong adhesives to prevent excessive tensile forces on the plantar fascia in view of a combination of a disposable foot protector that does not restrict the movement of the foot and acts as a cushioned house slipper, a protective foot pad that protects portions of the sole of a foot from contact with a surface and an ankle brace.

Claims 51 – 52

Claims 51 – 52 include the limitations of claim 44 along with the added limitation of a heel strap extending rearwardly from the stretch-resistant sole member with an adhesive layer to adhere to an outer skin tissue on a back of a heel of a foot.

The examiner restated the earlier rejection using the combination of Burgess and Holden and further acknowledged that neither Burgess nor Holden disclose thin flexible straps extending laterally outward from the opposite sides of the stretch-resistant sole member to adhere to a side or top of an arch of the foot. The Office Action cites Domenico as teaching a support device for prevention of ankle injuries having thin flexible straps extending laterally outward from opposite sides to partially encircle the talus, the navicular, the cuneiform and the cuboid region of the foot, an arch strap and a heel strap. The examiner's rationale for combining this reference with the combination of Burgess and Holden to render the claimed invention as obvious is:

“At the time of the invention, it would have been obvious to one skilled in art to have to make the device of Burgess and Holden to have straps having adhesive, as taught by of Domenico to have adhesive on top surface of the device to adhere the support device to the bottom of the foot and to secure the device better to sole of the foot.”³²

The examiner failed to provide any articulated reasoning with rational underpinnings other than merely to make a conclusory statement of obviousness. This conclusory statement fails to meet the standards articulated under *KSR*. The examiner has failed to provide articulated

32 Office Action mailed out on August 4, 2009, Section 6, last sentence of first full paragraph of Page 7.

reasoning with rational underpinnings to support a legal conclusion of obviousness as to why the claimed invention of an orthotic device with a stretch-resistant sole support and straps extending either over the arch, around the heel or over the front of a foot with strong adhesives to prevent excessive tensile forces on the plantar fascia in view of a combination of a disposable foot protector that does not restrict the movement of the foot and acts as a cushioned house slipper, a protective foot pad that protects portions of the sole of a foot from contact with a surface and an ankle brace that specifically discloses not restricting movement of the foot. Each of the cited references actually disclose the opposite, of not restricting the movement of the foot, and thus not restricting the extension and stretching of the outer skin tissue and the plantar fascia.

Claims 53 – 54

Claims 51 – 51 include the limitations of claim 44 along with the added limitation of a front strap having opposed ends extending laterally outward from opposite sides of the stretch-resistant sole member with an adhesive layer to adhere to an outer skin tissue on a side or top of an arch of the foot.

The examiner restated the earlier rejection using the combination of Burgess and Holden and further acknowledged that neither Burgess nor Holden disclose thin flexible straps extending laterally outward from the opposite sides of the stretch-resistant sole member to adhere to a side or top of an arch of the foot. The Office Action cites Domenico as teaching a support device for prevention of ankle injuries having thin flexible straps extending laterally outward from opposite sides to partially encircle the talus, the navicular, the cuniform and the cubiod region of the foot, an arch strap and a heel strap.

The examiner's rationale for combining this reference with the combination of Burgess and Holden to render the claimed invention as obvious is:

“At the time of the invention, it would have been obvious to one skilled in art to have to make the device of Burgess and Holden to have straps having adhesive, as taught by of Domenico to have adhesive on top surface of the device to adhere the support device to the bottom of the foot and to secure the device better to sole of the foot.”³³

33 Office Action mailed out on August 4, 2009, Section 6, last sentence of first full paragraph of Page 7.

The examiner failed to provide any articulated reasoning with rational underpinnings other than merely to make a conclusory statement of obviousness. This conclusory statement fails to meet the standards articulated under *KSR*. The examiner has failed to provide articulated reasoning with rational underpinnings to support a legal conclusion of obviousness as to why the claimed invention of an orthotic device with a stretch-resistant sole support and straps extending either over the arch, around the heel or over the front of a foot with strong adhesives to prevent excessive tensile forces on the plantar fascia in view of a combination of a disposable foot protector that does not restrict the movement of the foot and acts as a cushioned house slipper, a protective foot pad that protects portions of the sole of a foot from contact with a surface and an ankle brace. Each of the cited references actually disclose the opposite, of not restricting the movement of the foot, and thus not restricting the extension and stretching of the outer skin tissue and the plantar fascia.

Claims 56 - 60

Claims 56 – 60 include the limitations of an orthotic foot support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as at least one thin flexible strap or tab extending outward from the sole member beyond a sole of the foot with an adhesive layer to adhere directly to a skin surface on a side or top of the foot.

As discussed above, Burgess, Holden and Domenico, either taken singly in combination with one another fail to disclose, teach or suggest an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia. These references actually teach away from the claimed invention as they disclose devices that allow flexible movement of the foot rather restricting movement as necessary in the current invention.

The examiner stated that in respect to claims 56, and 60,

“the limitations of “restricting extension and stretching of the outer skin tissue on the sole of the foot”, when the device described above adheres to sole, it will obviously restrict extension of the skin and such that the tension forces applied to the plantar fascia from the forces on an arch of the foot which push the bones of the foot

downwardly, and are able to reduce tension in the plantar fascia (0027), when the device of Burgess is secured to the sole of the user's foot which will result in treating pain in at least one of the heel, or arch or ball of the foot (see paragraph 0016 and 0027) and controls the step to prevent extension and stretching, reduce tension on the plantar fascia of the foot.”³⁴

This rationale is incomprehensible. The Burgess reference does not use numbered paragraphs, and none of the cited references even disclose any concern with the plantar fascia. Apparently, the examiner is referring to paragraphs in the present application to provide some sort of rationale for the allegation that the resilient disposable foot protector of Burgess is stretch resistant.

Burgess is explicit that the sole member of the disposable foot protector is able to stretch to allow free and normal movement of the foot rather than restricting the movement of the foot. “Further, this allows increased mobility as the foot protector 100 is able to adjust of flexing of the foot during normal walking or running movements without inhibiting foot movement or causing the tack adhesive to tear away from the foot.” Column 3, lines 46 – 50. “the more the wearer can experience the comfort level of a conventional slipper” Column 3, lines 7 – 9. “Preferably, the fibers are randomly oriented to provide a good degree of resilience and flexibility.” Column 4, lines 8 -10.

Burgess teaches away from restricting the extension and stretching of the outer skin tissue. There is no rational basis for concluding that the disposable foot protector of Burgess “*will obviously restrict extension of the skin and such that the tension forces applied to the plantar fascia from the forces on an arch of the foot which push the bones of the foot downwardly, and are able to reduce tension in the plantar fascia (0027), when the device of Burgess is secured to the sole of the user's foot which will result in treating pain in at least one of the heel, or arch or ball of the foot (see paragraph 0016 and 0027) and controls the step to prevent extension and stretching, reduce tension on the plantar fascia of the foot.*” Instead, as disclosed by Burgess, the disposable foot protector operates to allow free and unrestricted movement of the foot.

34 Office Action mailed on August 4, 2009, last two lines on Page 7, first five lines on page 8.

The examiner has failed to provide articulated reasoning with rational underpinnings to support a legal conclusion of obviousness as to why the claimed invention of an orthotic device with a stretch-resistant sole support and straps extending either over the arch, around the heel or over the front of a foot with strong adhesives to prevent excessive tensile forces on the plantar fascia in view of a combination of a disposable foot protector that does not restrict the movement of the foot and acts as a cushioned house slipper, a protective foot pad that protects portions of the sole of a foot from contact with a surface and an ankle brace.

Claims 62 – 66

Claim 62 includes the limitations of a method for restricting extension and stretching of the plantar fascia of a human foot by the steps of

providing a thin flexible device of substantially uniform thickness

having a stretch-resistant sole member

sized and shaped to be conformed to an outer skin tissue on at least a portion of a sole of a wearer's foot in a region of the foot from a heel of a foot to a distal end of the toes, excluding the region under the four smaller toes; and

an adhesive layer on at least a portion of said sole member for adhering said device to the outer skin tissue on the sole of a wearer's foot,

said adhesive layer of sufficient adhesive strength to maintain said device in place on the outer skin tissue on the sole of the foot and said stretch-resistant sole engaging surface sufficiently stretch-resistant so as to restrict extension and stretching of the outer skin tissue when adhered thereto;

adhering said sole member to an outer skin tissue on a portion of a sole of a foot such that tension forces applied to the plantar fascia are shared with said device outer skin tissue, said adhesive layer and said sole member to restrict extension and stretching of an outer skin tissue on a sole of a foot, whereby; preventing excessive stress on a plantar fascia.

As discussed above, the disposable foot protector of Burgess, the protective attachment pad of Holden and the ankle support of Domenico fail to disclose a device or method for treating the plantar fascia of a human foot by restricting the extension and stretching of the plantar

fascia by using a thin flexible device having a stretch-resistant sole member with a strong adhesive to attach the stretch-resistant sole member to the sole of a foot such that tension of forces applied to the plantar fascia are shared with the device, the outer skin tissue, the adhesive layer and the sole member to restrict extension and stretching of an outer skin tissue on a sole of a foot to prevent excessive stress on a plantar fascia. None of these references are concerned with the plantar fascia. None of these references are concerned with restricting the extension and stretching of the outer skin tissue on a sole of a foot, and all three teach away from this limitation by promoting the free unrestricted movement of the foot. None of these references, taken singly or in combination with one another, would provide a rationale for one skilled in the art to modify their disclosures to provide an orthotic device that has a stretch-resistant sole member with an adhesive sufficiently strong that when the stretch-resistant sole member is secured by the adhesive to the outer skin tissue adjacent the plantar fascia, the outer skin tissue is restricted from extending and stretching so that the excessive tensile forces on the plantar fascia are prevented.

The examiner failed to provide any articulated reasoning with rational underpinnings as to meet the legal conclusion of obviousness when none of the references disclose, suggest or teach the use of a stretch-resistant sole member that excludes the region under the toes, with a strong adhesive to restrict extension and stretching of the outer skin tissue to prevent excessive tensile forces on the plantar fascia.

Claims 63 – 66 include the added limitations concerning the arch and heel straps, which as earlier discussed are not obvious. The examiner has failed to provide articulated reasoning with rational underpinnings to support a legal conclusion of obviousness as to why the claimed invention of an orthotic device with a stretch-resistant sole support and straps extending either over the arch, around the heel or over the front of a foot with strong adhesives to prevent excessive tensile forces on the plantar fascia in view of a combination of a disposable foot protector that does not restrict the movement of the foot and acts as a cushioned house slipper, a protective foot pad that protects portions of the sole of a foot from contact with a surface and an ankle brace.

4. Whether Claims 45, 72, 75-76, 78 and 80 are unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden and in further view of Desnoyers.

Claims 45, 72, 75, 76, 78 and 80 include the limitations of an orthotic foot support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as the added limitations of excluding a resilient cushion layer and of the sole member having a ratio of elongation to tensile strength that is less than 0.9

The examiner agreed “*that the Burgess discloses to have cushion effect (column 3 lines 16-20), however, it has been interpreted by the examiner that even bottom of foot sole have natural cushion in form of muscles, then how one claim limitation to not have cushion layer, since naturally human body is cushion at bottom of feet sole in form of muscles.*”³⁵ This rationale to the extent that it can be understood, is incorrect.

First, Applicant, in claim 75, is not claiming the human foot as a limitation, but an orthotic foot support device for reducing stress on the plantar fascia of a foot. Thus, the muscles of the human foot are not a specific limitation of claim 75. Claim 75 explicitly excludes a cushion layer as a claimed limitation.

Second, Burgess specifically, as acknowledged by the examiner, is disclosing a resilient cushion layer so that the disposable foot protector will feel like a conventional slipper. According to the examiner’s logic, such a cushion is unnecessary as this is provided by the muscles of the human foot. The examiner has failed to provide articulated reasoning as to why the muscles of the human foot meet the limitation of excluding a cushion layer on an orthotic device.

In regard to the limitation of the ratio of elongation to tensile strength that is less than 0.9, the examiner acknowledges that neither Burgess or Holden disclose this limitation. The examiner specifically states that: “*However, Burgess and Holden does not disclose that the sole member has a ratio of elongation (%) to tensile strength (lb/in-width) that is less than 0.9, whereby providing a balanced combination of strength and resistance to elongation.*”³⁶

³⁵ Office Action mailed out August 4, 2009, Page 8, lines 5 – 9 of Section 7.

³⁶ Office Action mailed out August 4, 2009, Page 8, lines 9 – 12 of Section 7.

The examiner alleged that it would be obvious to use the teaching of Desnoyers of a pressure sensitive tape having a ratio of elongation to tensile strength ratio of about 3 to 1 as meeting the limitations. The examiner is incorrect in this assertion for several reasons.

First, Desnoyers does not disclose a ratio of elongation to tensile strength ratio of about 3 to 1, but instead discloses that the tape disclosed therein has a crosswise tensile strength to lengthwise tensile strength of about 3 to 1.³⁷ This is a completely different property than the claimed limitation of a ratio of elongation to tensile strength.

Second, Desnoyers actually discloses a tape that is highly stretchable: *“These tapes, preferably, have an extensibility at break of 45% or more in the lengthwise direction”*.³⁸ Also, Desnoyers discloses a *“tape having a relatively high longitudinal extensibility”*.³⁹ Desnoyers clearly discloses the opposite as the limitation from the presently claimed invention and simply does not disclose the limitation of a ratio of elongation to tensile strength of less than 0.9 as the claim requires.

Third, the examiner presents no rationale for modifying the combination of Burgess and Holden in view of Desnoyers. The examiner simply states that *“At the time of the invention was made, it would have been obvious to one having ordinary skill in the art to use the material to make the device of Burgess and Holden to have tensile strength to ratio of elongation, as taught by Desnoyers to have resistance to tearing.”*⁴⁰ This conclusory statement falls far short of the standard required under KSR of providing “some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. Even the limited reasoning put forth by the examiner of *“to have resistance to tearing”* has absolutely no relevance to the claimed invention where the ratio of elongation to tensile strength of less than 0.9 is for the purpose of providing a balanced combination of strength and resistance to elongation, not for resistance to tearing. The claimed invention is not concerned with tearing, but is concerned with stretch-resistance.

37 See Desnoyers, claim 2 - “a ratio of lengthwise tensile strength to crosswise tensile strength of at least about 3 to 1.” See column 3, lines 25 – 26 “a corresponding tensile strength ratio of at least about 3 to 1.”

38 Desnoyers, column 4, lines 67 – 70

39 Claim 1 of Desnoyers, column 7, lines 3 – 4.

40 Office Action mailed out August 4, 2009, Pages 8 – 9, last paragraph of Section 7.

The examiner has fallen well short of providing a rational basis for concluding that the disclosures of Burgess, Holden, and Desnoyers would render the claimed invention as obvious.

5. Whether Claim 46 is unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden and in further view of Desnoyers.

Claim 46 includes the limitations of an orthotic foot support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as the sole member being formed of a single layer of fabric material having a uniform thickness of less than 30 mil. (0.762 mm).

As discussed above, none of the references taken in either singly or in combination with one another teach, suggest, disclose or in any way render obvious to one skilled in the art, an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia. Further, both Burgess and Holden clearly disclose foot protectors that provide cushioning for comfort. Burgess discloses a disposable foot protector that is between 1 mm and 5 mm, preferably 2 mm.⁴¹ The claimed limitation of no more than .762 mm is about 25% less than the minimum range disclosed by the Burgess specification and is dramatically less than the minimum thickness range of 2 mm to 5 mm, claimed by Burgess. First, a thicker cushioning layer as suggested by Burgess would render the device of the present invention, less capable of being utilized under socks or worn inside normal footwear as an orthotic device. Second, this minimum limitation of Burgess is necessary in order to provide the resilience and cushion effect to provide comfort to the wearer.

The use of a thin sole member of less than 30 mils (.762 mm) would not provide adequate cushioning for comfort and thus would destroy the functioning of the reference, or make it unsatisfactory for its intended purpose. (MPEP 2143.01).⁴² Additionally, these references are not

⁴¹ "The foot protector 100 preferably has a thickness in the range of about 1 mm to about 5 mm, with a thickness of about 2 mm, for example, being particularly advantageous. This foot protector thickness has many advantages. First, a thickness of about 1 mm to about 5 results in a foot protector 100 that has enough resilience, or cushion effect, to provide comfort to the foot of the wearer, but which is lightweight enough that it can be held to the foot 200 with an adhesive having relatively low tack, or stickiness." Column 3, lines 13 - 21

⁴² Changes in mere size or shape in some circumstances may be considered obvious combinations or

formed of a single layer of fabric and, thus the proposed combination fails to teach all claim limitations.

There is no rational basis for modifying the disclosure of Burgess in such a manner that would render it unworkable for its intended purpose in order to meet the claimed limitations or using the disclosure of Burgess to render the claimed invention ineffective.

6. Whether Claims 47, 61, 67 and 69 are unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden and in further view of Huddleston et al.

Claims 47, 61, and 67 include the limitations of an orthotic foot support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as the sole member exhibiting less than 15% elongation when subjected to a tensile load equivalent to 25 pounds/inch⁴³ while claim 69 includes those limitations plus the limitation of being less than 30 mils thick.

As discussed above, none of the references taken in either singly or in combination with one another teach, suggest, disclose or in any manner render obvious to one skilled in the art, an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia. Further, both Burgess and Holden teach away from a sole member that is stretch resistant, as discussed above. The examiner acknowledges that neither reference discloses a thickness of less than 30 mils (claim 69), but states that would be mere design choice, despite that a thicker sole member would render the device less effective. The examiner acknowledges that neither reference include the limitation of less than 15% elongation when subjected to a tensile load equivalent to 25 pounds. The examiner cites Huddleston et al. as disclosing this feature and that somehow it would be obvious to modify the combined references to provide these features.

modification, but would not be considered obvious in the case where doing so would destroy the functioning of the reference, or make it unsatisfactory for its intended purpose. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." (MPEP 2143.01)

⁴³ The inclusion of "pounds/inch" is a typographical error. The specification supports the use of "pounds" instead of "pounds/inch". An amendment has been filed to correct this typographical error prior to filing of the brief, but had not yet been entered by the examiner.

Huddleston et al. teaches an aluminum tape for use with rigid fiberglass air ducts that has a tensile strength greater than 25 pounds. *However, Huddleston et al. fails to disclose whether or not the metal foil adhesive exhibits less than 15% elongation when subjected to a tensile load equivalent to 25 pounds.* There simply is no disclosure anywhere in Huddleston et al. of the elongation of the aluminum tape regarding the elongation. Apparently the examiner mistakenly misinterpreted the discussion of the tensile strength of the aluminum tape⁴⁴. No where is the elongation discussed in this reference. Thus Huddleston et al. fails to disclose this critical limitation, thus the proposed combination fails to teach all claim limitations. Further, one skilled in the art would not consider using an aluminum metal tape, typically used in repairing rigid fiberglass air ducts as an orthotic device secured to the outer skin tissue. The resulting product would severely damage the skin and foot of a wearer.

There is no rational basis for modifying the combined references as suggested by the examiner, particularly when several of the claimed limitations are not even disclosed, suggested or taught by the references. The examiner has failed to provide articulated reasoning with rationale underpinnings to support the legal conclusion of obviousness when the references fail to disclose any of the limitations and there is no common sense rationale as to why anyone would combine these references or why the claimed limitations would be obvious in view of these references.

7. Whether Claim 68 is unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden and in further view of Huddleston et al.

Claim 68 includes the limitations of an orthotic foot support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as a sole member having a single layer of fabric with adhesive layer having a thickness of less than 30 mils and exhibiting less than 15% elongation when subjected to a tensile load equivalent to 25 pounds/inch⁴⁵.

⁴⁴ Huddleston et al., Column 1, lines 48 – 55.

⁴⁵ The inclusion of “pounds/inch” is a typographical error. The specification supports the use of “pounds” instead of “pounds/inch”. An amendment has been filed to correct this typographical error prior to filing of the brief, but had not yet been entered by the examiner.

As discussed above, none of the references taken in either singly or in combination with one another teach, suggest or disclose an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia. Further, both Burgess and Holden teach away from a sole member that is stretch resistant, as discussed above. The minimum thickness of Burgess necessary for it to perform its intended function of cushioning the foot is 25% greater than the maximum thickness of the Applicant's claimed sole member. Further, Huddleston et al. teaches an aluminum metal tape for use with rigid fiberglass air ducts that has a tensile strength greater than 25 pounds/inch. However, Huddleston et al. fails to disclose whether or not the metal foil adhesive exhibits less than 15% elongation when subjected to a tensile load equivalent to 25 pounds. Thus Huddleston et al. fails to disclose this critical limitation. Further, one skilled in the art would not consider using an aluminum metal tape, typically used in repairing rigid fiberglass air ducts as an orthotic device secured to the outer skin tissue. The resulting product would not be comfortable against the skin nor would it easily conform to the three dimension contours of the foot.-

There is no rational basis for modifying the Burgess as suggested by the examiner, particularly when there is no disclosure of several of the features or reason to modify the reference to provide these features.

8. Whether Claims 73 – 74 are unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden and in further view of Desnoyers.

Claims 73 - 74 includes the limitations of an orthotic foot support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as a sole member having a ratio of elongation to tensile strength that is less than 0.9 and having a woven micro-fiber layer (claim 73) or being less than 30 mils (claim 74).

As discussed above, none of the references taken in either singly or in combination with one another teach, suggest or disclose **an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia.** Further, both Burgess and Holden clearly disclose foot

protectors that provide cushioning for comfort. These references teach away from the use of a thin sole member of less than 30 mils as it would not provide adequate cushioning for comfort, teach away from a stretch-resistant sole member and an adhesive sufficiently strong to restrict the outer skin tissue from extending and stretching.

Woven fabric is defined as: A planar structure produced by interlacing two or more sets of yarns, fibers, rovings, or filaments where the elements pass each other essentially at right angles and one set of elements is parallel to the fabric axis. Burgess on the other hand defines the material for the disposable foot protectors as “Preferably, the fibers are randomly oriented to provide a good degree of resilience and flexibility.” The random orientation of the fibers of the material of Burgess is intended to provide resilience and flexibility while the orientation of the fibers at right angles to one another with one set of fibers parallel to the axis of the fabric is intended to provide stretch-resistance. **Burgess fails to disclose a woven fabric**, and to modify Burgess to use a woven fiber would render the Burgess device unworkable for its intended purpose of resilience and flexibility and suggest that Burgess actually teaches away from such a limitation.

The examiner specifically states that: *“However, Burgess and Holden does not disclose that the sole member has a ratio of elongation (%) to tensile strength (lb/in-width) that is less than 0.9, whereby providing a balanced combination of strength and resistance to elongation.”*⁴⁶

The examiner alleged that it would be obvious to use the teaching of Desnoyers of a pressure sensitive tape having a ratio of elongation to tensile strength ratio of about 3 to 1 as meeting the limitations. The examiner is incorrect in this assertion for several reasons.

First, Desnoyers does not disclose a ratio of elongation to tensile strength ratio of about 3 to 1, but instead discloses that the tape disclosed therein has a crosswise tensile strength to lengthwise tensile strength of about 3 to 1.⁴⁷ This is a completely differing material property.

Second, Desnoyers actually discloses a tape that is highly stretchable: *“These tapes, preferably, have an extensibility at break of 45% or more in the lengthwise direction”*.⁴⁸ Also,

46 Office Action mailed out August 4, 2009, Page 8, lines 9 – 12 of Section 7.

47 See Desnoyers, claim 2 - “a ratio of lengthwise tensile strength to crosswise tensile strength of at least about 3 to 1.” See column 3, lines 25 – 26 “a corresponding tensile strength ratio of at least about 3 to 1.”

48 Desnoyers, column 4, lines 67 – 70

Desnoyers discloses a “*tape having a relatively high longitudinal extensibility*”.⁴⁹ Desnoyers clearly teaches away from the presently claimed invention and simply does not disclose the limitation of a ratio of elongation to tensile strength of less than 0.9 as the claim requires.

Third, the examiner presents no rationale for modifying the combination of Burgess and Holden in view of Desnoyers to arrive at the claimed invention. The examiner simply states that “*At the time of the invention was made, it would have been obvious to one having ordinary skill in the art to use the material to make the device of Burgess and Holden to have tensile strength to ratio of elongation, as taught by Desnoyers to have resistance to tearing.*”⁵⁰ This conclusory statement falls far short of the standard required under KSR of providing “some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. Even the limited reasoning put forth by the examiner of “*to have resistance to tearing*” has absolutely no relevance to the claimed invention where the ratio of elongation to tensile strength of less than 0.9 is for the purpose of providing a balanced combination of strength and resistance to elongation, not for resistance to tearing.

The examiner has fallen well short of providing a rational basis for concluding that the disclosures of Burgess, Holden, and Desnoyers would render the claimed invention as obvious.

9. Whether Claims 77 and 79 are unpatentable under 35 U.S.C. §103(a) as being obvious over Burgess in view of Holden and in further view of Desnoyers and in further view of Huddleston et al.

Claims 77 and 79 includes the limitations of an orthotic foot support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as a sole member having a single layer of fabric with adhesive layer having a thickness of less than 30 mils and exhibiting less than 15% elongation when subjected to a tensile load equivalent to 25 pounds and having a ratio of elongation to tensile strength of less than 0.9.

As discussed above, none of the references taken in either singly or in combination with

⁴⁹ Claim 1 of Desnoyers, column 7, lines 3 – 4.

⁵⁰ Office Action mailed out August 4, 2009, Pages 8 – 9, last paragraph of Section 7.

one another teach, suggest or disclose an **orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia**. Further, both Burgess and Holden teach away from a sole member that is stretch resistant, as discussed above. Huddleston et al. teaches an aluminum metal tape for use with rigid fiberglass air ducts that has a tensile strength greater than 25 pounds/inch. However, Huddleston et al. **fails to disclose whether or not the metal foil adhesive exhibits less than 15% elongation when subjected to a tensile load equivalent to 25 pounds/inch**. Thus Huddleston et al. fails to disclose this critical limitation. Additionally, these references are not formed of *“a single layer of fabric”* and, thus the proposed combination again fails to teach all claim limitations.

The examiner specifically states that: *“However, Burgess and Holden does not disclose that the sole member has a ratio of elongation (%) to tensile strength (lb/in-width) that is less than 0.9, whereby providing a balanced combination of strength and resistance to elongation.”*⁵¹

The examiner alleged that it would be obvious to use the teaching of Desnoyers of a pressure sensitive tape having a ratio of elongation to tensile strength ratio of about 3 to 1 as meeting the limitations. The examiner is incorrect in this assertion for several reasons.

First, Desnoyers does not disclose a ratio of elongation to tensile strength ratio of about 3 to 1, but instead discloses that the tape disclosed therein has a crosswise tensile strength to lengthwise tensile strength of about 3 to 1.⁵²

Second, Desnoyers **actually discloses a tape that is highly stretchable**: *“These tapes, preferably, have an extensibility at break of 45% or more in the lengthwise direction”*.⁵³ Also, Desnoyers discloses a *“tape having a relatively high longitudinal extensibility”*.⁵⁴ Desnoyers clearly teaches away from the presently claimed invention and simply does not disclose the limitation of a ratio of elongation to tensile strength of less than 0.9 as the claim requires.

Third, the examiner presents no rationale for modifying the combination of Burgess and Holden in view of Desnoyers to arrive at the claimed invention. The examiner simply states that

51 Office Action mailed out August 4, 2009, Page 8, lines 9 – 12 of Section 7.

52 See Desnoyers, claim 2 - “a ratio of lengthwise tensile strength to crosswise tensile strength of at least about 3 to 1.” See column 3, lines 25 – 26 “a corresponding tensile strength ratio of at least about 3 to 1.”

53 Desnoyers, column 4, lines 67 – 70

54 Claim 1 of Desnoyers, column 7, lines 3 – 4,

"At the time of the invention was made, it would have been obvious to one having ordinary skill in the art to use the material to make the device of Burgess and Holden to have tensile strength to ratio of elongation, as taught by Desnoyers to have resistance to tearing."⁵⁵ This conclusory statement falls far short of the standard required under KSR of providing "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness". Even the limited reasoning put forth by the examiner of "to have resistance to tearing" has absolutely no relevance to the claimed invention where the ratio of elongation to tensile strength of less than 0.9 is for the purpose of providing a balanced combination of strength and resistance to elongation, not for resistance to tearing.

The examiner has fallen well short of providing articulated reasoning with rational underpinnings for concluding that the disclosures of Burgess, Holden, Desnoyers and Huddleston et al. would render the claimed invention as obvious.

Secondary Considerations

According to MPEP 716.01 (a): "The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983) that "evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." Such evidence might give light to circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or unobviousness, such evidence may have relevancy. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *In re Palmer*, 451 F.2d 1100, 172 USPQ 126 (CCPA 1971); *In re Fielder*, 471 F.2d 640, 176 USPQ 300 (CCPA 1973). The *Graham v. John Deere* pronouncements on the relevance of commercial success, etc. to a determination of obviousness were not negated in *Sakraida v. Ag Pro*, 425 U.S. 273, 189 USPQ 449 (1979) or *Anderson's-Black Rock Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969), where reliance was placed upon *A&P Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 87 USPQ 303 (1950). See *Dann v. Johnston*, 425 U.S. 219, 226 n.4, 189 USPQ 257, 261 n. 4 (1976)."

Evidence of such secondary consideration is provided in Exhibit B, in the form of an affidavit of a medical practitioner who has experience with the presently claimed invention. This

⁵⁵ Office Action mailed out August 4, 2009, Pages 8 – 9, last paragraph of Section 7.

objective evidence is dispositive of the nonobviousness of the presently claimed invention. A key limitation found in the claims of a space “stretch-resistant sole member sufficiently stretch-resistant to restrict extension and stretching of an outer skin tissue on the sole of a foot, when adhered thereto” provides the nexus between the ability of the product of the claimed invention to satisfy the long felt need of treating plantar fasciitis as set forth in the declaration of Dr. Delamos. This exhibit was entered into the record on December 3, 2008.

Conclusion

In view of the above discussion and arguments, the rejections of claims 44 – 80 should be withdrawn. Throughout the long prosecution history of this application including seven (7) rejections based primarily on the Burgess reference, the examiner has failed to provide an appropriate *prima facie* case of anticipation or obviousness.

Respectfully submitted,

Date: December 16, 2009

By: /glennlwebb32668/

Glenn L. Webb, Reg. No. 32,668
PO 3788
Durango, CO 81302
303 816 4893

XI. CLAIMS APPENDIX

44. An orthotic foot support device for a human foot, comprising:

a foot support device having a thin flexible stretch-resistant sole member of uniform thickness having a shape matching less than the entire outline of a sole of a wearer's foot to which the device is to be applied and sized to cover only a portion of the wearer's sole; and

an adhesive layer on said sole member for securely adhering said device directly to an outer skin tissue on the sole of the foot, and at least one protective cover removably disposed over said adhesive layer which, when removed, exposes said adhesive layer;

said stretch-resistant sole member sufficiently stretch-resistant to restrict extension and stretching of an outer skin tissue on the sole of a foot, when adhered thereto, and

said adhesive layer of sufficient adhesion to maintain said stretch-resistant sole member in adhesive engagement with an outer skin tissue on the sole of the foot, such that tension forces applied to a plantar fascia are shared with an outer skin tissue, said adhesive layer, and said sole member to restrict extension and stretching of an outer skin tissue of a sole of a wearer's foot, whereby preventing excessive tensile stress in a plantar fascia.

45. The device according to claim 44, wherein

said sole member has a ratio of elongation to tensile strength (lb/in-width) that is less than 0.9 to provide a balanced combination of strength and resistance to elongation

46. The device according to claim 45, wherein

said stretch-resistant sole member is formed of a single layer of fabric material having a uniform thickness of less than 30 mils (0.762 mm).

47. The device according to claim 44, wherein

said stretch-resistant sole member exhibits than 15% elongation when subjected to a tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance to ASTM D3759.

48. The device according to claim 44, further comprising:

a thin flexible arch strap having opposed ends extending laterally outward from opposite sides of said stretch-resistant sole member;

an adhesive layer on said arch strap for adhering said arch strap directly to an outer skin tissue on a side or top of an arch of a foot, and a protective cover removably disposed over said adhesive layer which, when removed, exposes said adhesive layer;

said arch strap, when adhered to an outer skin tissue on a side or top of an arch of a foot, provides a further means to maintain said sole member in position on a sole of a foot of a wearer.

49. The device according to claim 48, wherein

said arch strap is secured to said device by an adhesive.

50. The device according to claim 48, wherein

said arch strap is integrally formed with said device.

51. The device according to claim 44, further comprising:

at least one thin flexible heel strap extending rearwardly from said sole member of said device;

an adhesive layer on said heel strap for adhering said heel strap directly to an outer skin tissue on a back of a heel of a foot, and a protective cover removably disposed over said adhesive layer which, when removed, exposes said adhesive layer;

said heel strap, when adhered to an outer skin tissue of a heel of a foot provides a further means to maintain the position of said sole member on a sole of a foot.

52. The device according to claim 51, wherein

said heel strap is integrally formed with said device.

53. The device according to claim 44, further comprising:

a thin flexible front strap having opposed ends extending laterally outward from opposite sides of said stretch-resistant sole member in a position to at least partially overlap a top of a foot above a ball portion of a foot;

an adhesive layer on said front strap for adhering said front strap directly to an outer skin tissue on a side and a top of a ball portion of a foot, and a protective cover removably disposed over said adhesive layer which, when removed, exposes said adhesive layer;

said front strap, when adhered to an outer skin tissue on a side and a top of a ball portion of a foot provides a further means to maintain said sole member in position on the sole of a wearer's foot.

54. (Previously Presented) The device according to claim 53, wherein

said front strap is integrally formed with said device.

55. The device according to claim 44 wherein

said sole member is comprised of a single woven fabric layer, an adhesive layer and a protective cover layer removeably disposed on said adhesive layer.

56. (Previously Presented) An orthotic foot support device for a human foot, comprising:

a foot support device having a thin flexible substantially stretch-resistant sole member sized and shaped to engage an outer skin surface of at least a portion of a sole of an individual's foot to which said device is to be applied and an adhesive layer on said sole member for adhering said sole member directly to an outer skin surface of a sole of a foot; and

at least one thin flexible strap or tab having an end extending outward from said sole member beyond a sole of a foot, and an adhesive layer on said strap or tab for adhering said strap or tab directly to an outer skin surface on a side or a top of a foot, wherein said strap or tab adhered to an outer skin surface of a foot provides further means for maintaining said sole member in adhesive engagement with the skin tissue on a sole of a foot; said sole member is

sufficiently stretch-resistant to restrict extension and stretching of an outer skin surface of a sole when adhered thereto and said adhesive layer on said sole member is of sufficient adhesion to maintain said sole member on an outer skin surface of a sole of a foot so that tension forces applied to a plantar fascia are shared with said outer skin surface, said adhesive layer, and said stretch resistant sole member to restrict stretching and extension of an outer skin tissue on a sole of a foot; whereby excessive or damaging tensile stress in a plantar fascia is prevented.

57. The device according to claim 56, wherein

said at least one thin flexible strap or tab comprises an arch strap having at least one end extending laterally outward from a side of said sole member in a position to engage a side and at least a portion of a top of an arch of a foot;

said arch strap, when adhered to an outer skin surface on the sides a side and a top of a arch of a foot, provides a further means to maintain said sole member in an adhesively engaged position with a sole of a foot.

58. The device according to claim 56, wherein

said at least one thin flexible strap or tab comprises at least one heel strap or heel tab extending from said sole engaging surface of said device, and an adhesive layer on said heel strap or heel tab for adhering said heel strap or heel tab directly to an outer skin surface on a heel of a foot;

said heel strap or heel tab, when adhered to an outer skin surface of a heel of a foot providing provides further means for maintaining said sole member in adhesive engagement with a sole of a foot.

59. The device according to claim 56, wherein

said at least one thin flexible strap or tab comprises a front strap having at least one end extending laterally outward from a side of said stretch-resistant sole member in a position to at least partially overlap a top of a foot above a ball portion of a foot, and an adhesive layer on said front strap for adhering said front strap directly to an outer skin surface surfaces on a side and a top of a ball portion of a foot;

said front strap, when adhered to an outer skin surface surfaces on a side and a top of a ball portion of a foot provides further means for maintaining said sole member in engagement with a sole of a foot.

60. A support device for a human foot, comprising:

a thin flexible foot support device of substantially uniform thickness having a stretch-resistant sole member sized and shaped to engage and to cover an outer skin surface on at least a portion a sole of a wearer's foot and extend along at least a portion a plantar fascia region of the foot, an adhesive layer on said sole member for adhering said sole member directly to an outer skin tissue on a sole of a wearer's foot, and a protective cover removably disposed over said adhesive layer which, when removed, exposes said adhesive layer; and

a thin flexible arch strap member having a mid portion and opposed ends, an adhesive layer on said arch strap, and a protective cover removably disposed over said adhesive layer which, when removed, exposes said adhesive layer, wherein said arch strap when adhered to a foot provides a further means for maintaining said sole member in engagement with a sole of a wearer's foot; whereby

said adhesive layer on said sole engaging surface is of sufficient adhesion to maintain said device in place on the outer skin surface on the sole of the foot and said stretch-resistant sole engaging surface is sufficiently stretch-resistant to restrict extension and stretching of the outer skin surface on the sole of the foot, when adhered thereto, so that tension forces applied to the a plantar fascia are shared with said outer skin surface, said adhesive layer and said sole engaging surface to restrict extension and stretching of a plantar fascia.

61. The support device according to claim 60, wherein wherein said stretch-resistant sole member exhibits less than 15% elongation when subjected to a tensile load (lb/in-width) equivalent to 25 pounds/inch in accordance with test methods equivalent to ASTM D3759.

62. A method for restricting extension and stretching of the plantar fascia of a human foot, comprising the steps of:

providing a thin flexible device of substantially uniform thickness having a stretch-resistant sole member sized and shaped to be conformed to an outer skin tissue on at least a portion of a sole of a wearer's foot in a region of the foot from a heel of a foot to a distal end of

the toes, excluding the region under the four smaller toes; and an adhesive layer on at least a portion of said sole member for adhering said device to the outer skin tissue on the sole of a wearer's foot, said adhesive layer of sufficient adhesive strength to maintain said device in place on the outer skin tissue on the sole of the foot and said stretch-resistant sole engaging surface sufficiently stretch-resistant so as to restrict extension and stretching of the outer skin tissue when adhered thereto;

adhering said sole member to an outer skin tissue on a portion of a sole of a foot such that tension forces applied to the plantar fascia are shared with said device outer skin tissue, said adhesive layer and said sole member to restrict extension and stretching of an outer skin tissue on a sole of a foot, whereby; preventing excessive stress on a plantar fascia.

63. The method according to claim 62, comprising the further steps of:

adhering opposed ends of a thin flexible arch strap extending laterally outward from opposite sides of said stretch-resistant sole member to the outer skin tissue on the sides or top of an arch of a foot to provide a further means for maintaining said stretch resistant sole member in adhesive contact with a sole of a foot.

64. The method according to claim 63, wherein

said steps of adhering said arch strap include a preliminary step of adhering a midportion of said arch strap to an underside of said device, and thereafter

adhering said opposed ends of said arch strap to an outer skin tissue on the sides or top of an arch of a foot in a position to at least partially encircle a talus, a navicular, a cuneiform, or a cuboid region of a foot.

65. The method according to claim 62, comprising the further steps of:

adhering a thin flexible heel strap extending from said sole member of said device to an outer skin tissue on a back or a side of a heel of a foot to provide a further means for maintaining said sole member in adhesive engagement with a sole of a foot.

66. The method according to claim 62, wherein

said sole engaging surface is sized and shaped to engage the outer skin tissue on a portion of the sole of a foot and to extend from a heel of a foot to about a ball portion of a foot, and comprising the further steps of:

adhering opposed ends of a thin flexible strap extending laterally outward from opposite sides of said stretch-resistant sole member to the outer skin tissue on a side or a top of a foot to provide a further means for maintaining said sole member in engagement with a sole of a foot; and wherein said device is used for the treatment or prevention of plantar fasciitis.

67. The device according to claim 56, wherein

said stretch-resistant sole member has a thickness of less than 30 mils (0.762 mm) and exhibits less than 15% elongation when subjected to a tensile load (1 lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759.

68. The device according to claim 61, wherein said stretch-resistant sole member is comprised of a single layer of fabric with an adhesive layer wherein said fabric has a thickness of less than 30 mils (0.762 mm).

69. The method according to claim 62, comprising the further steps of: removing at least one protective cover removeably disposed over said adhesive layer which, when removed, exposes said adhesive layer, and wherein said sole member is of a substantially uniform thickness of less than less than 30 mils (0.762 mm) and exhibits less than 15% elongation when subjected to a tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with the test methods of ASTM D3759.

70. An orthotic foot support device for reducing stress on the plantar fascia of a wearer's foot, said device comprising:

a stretch resistant, uniform thickness sole support, having a shape matching less than an entire outline of a sole of an individual's foot where the device is to be applied;

an adhesive layer on said sole support for attaching said sole support to a sole of the wearer's foot such that said sole support absorbs tensile stress thus preventing extension and stretching of tissue on a bottom of the wearer's foot on which a said sole support is attached, whereby preventing excessive tensile stress in a plantar fascia.

71. The device of claim 70, wherein said device, further comprises;

- a protective cover layer detachably disposed on said adhesive layer,
- a strap to be affixed to a foot generally transversely to said sole support;
- an adhesive layer on said strap for adhering said strap to an outer skin surface of a top of the foot;
- a protective cover layer detachably disposed on said strap.

72. The device of claim 70 wherein said sole support has a size less than the size of a entire sole of a wearers' foot, and wherein said sole support has a ratio of elongation (%) to tensile strength (lb/in-width) that is less than 0.9 to provide a balanced combination of strength and resistance to elongation.

73. The device of claim 72 wherein said sole support includes a woven micro-fiber layer.

74. The device of claim 72 wherein said sole support is less than 30 mils (.762mm) thick, whereby being thin enough to be worn inside socks or shoes.

75. An orthotic foot support device for reducing stress on the plantar fascia of a wearer's foot, said device comprising:

- a thin flexible stretch resistant, sole support, shaped to cover only a portion the sole of a wearer's foot on which the device is to be applied; and wherein said sole support does not including a resilient cushion layer; and wherein said sole support has a ration of elongation (%) to tensile

strength (lb/in-width) that is less than 0.9 providing a balanced combination of strength and resistance to elongation;

an adhesive layer on said sole support for attaching said sole support to a sole of the wearer's foot so that extension and stretching of tissue on a bottom of the wearer's foot is restricted, whereby preventing excessive tensile stress in a plantar fascia.

76. The device of claim 75, wherein said device, further comprises;

a protective cover layer detachably disposed on said adhesive layer,
a strap to be affixed to the wearer's foot with an end extending outwardly from said sole support;

an adhesive layer on said strap for adhering said strap to an outer skin surface of the wearer's foot;

a protective cover layer detachably disposed on said strap.

77. The device of claims 75 wherein said sole support includes a woven fabric layer which exhibits less than 15 percent elongation when subjected to a 25 lb tensile load under test conditions specified in ASTM D3759, wherein said device includes a protective cover removeably disposed on said adhesive layer and wherein said device is to be used in the treatment of plantar fasciitis or in the prevention of excessive e tensile stress in a plantar fasciitis.

78. A plantar fascia support device for a human foot comprising:
a uniform thickness, sole support, shaped to cover only a portion of a bottom of a wearer's foot where the device is to be applied, wherein said sole support has a ratio of elongation to tensile strength (lb/in-width) that is less than 0.9 to provide a balanced combination of strength and resistance to elongation;
an adhesive layer on said sole support for securely adhering said sole support to an outer skin of a sole of the wearer's foot.

79. The device of claims 78 wherein said sole support is comprised of a single non-resilient support layer, a uniformly applied adhesive layer and a protective cover layer detachably disposed on said adhesive layer; and wherein said sole support exhibits less than 15 percent elongation when subjected to a 25 lb tensile load under test conditions equivalent to those specified in ASTM D3759.

80. The device of claim 78, wherein said device, further comprises;
a protective cover layer detachably disposed on said adhesive layer,
a strap to be affixed to a wearer's foot generally transversely to said sole support;
an adhesive layer on said strap for adhering said strap to an outer skin surface of a top or a side of the wearer's foot;
a protective cover layer detachably disposed on said strap.

IX. EVIDENCE APPENDIX

Custom Made Orthotics

Our custom made orthotics are made to order. Research has shown that custom made orthotics are the most effective.

Foot Pain?

A custom made orthotic can help to relieve foot pain. The orthotic is made to fit your foot, and is designed to provide the most effective support.

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**Definition of Orthotic**

Orthotic: A support brace, or appliance, to support, align, prevent, or correct the function of movable parts of the body. Since inserts are orthotics that are often used to correct an abnormal, or irregular walking pattern, by altering slightly the angles at which the foot strikes a walking or running surface. Other orthotics include foot braces, lumbar/neck supports, knee braces, and wrist supports.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Donald P. Bushby)
) ART UNIT: 3772
Serial No: 10/817,172)
) Examiner: Tarla R. Patel
Filed : April 2, 2004)
)
For : SYSTEM FOR TREATMENT OF PLANTAR FASCIITIS)

Mail Stop Amendment

The Hon. Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313 -1450

November 18, 2008

DECLARATION UNDER 37 C.F.R. 1.132

My name is David M. de Lemos M.D., Assistant Professor, Department of Pediatrics, Section of Emergency Medicine, Baylor College of Medicine, Houston, Texas, and I hereby make the following declarations:

I am familiar with Mr. Donald P. Bushby and his device for the treatment of plantar fasciitis for which the above referenced patent application is pending. I have no financial relationship with Mr. Bushby and hold no financial interest in his invention.

My wife (Helen) has suffered from plantar fasciitis for a number of years. Her condition limited her ability to run and particularly to compete in marathons. After trying many forms of treatment over a period of years such as custom orthotics and nighttime bracing with only limited success, we heard second hand about Mr. Bushby's invention. Contact was made between Mr. Bushby and us, and my wife began a brief trial of using Mr. Bushby's device shortly thereafter.

It is my opinion, as a medical professional with medical and personal knowledge of the debilitating effects of plantar fascia, that the stretch resistant sole portion with a strong adhesive layer restricts the extension and stretching of the outer skin tissue. This unique combination shares the tension forces that are applied to the plantar fascia with the outer skin tissue, adhesive layer and stretch resistant sole member to prevent excessive tensile stress in the plantar fascia. The device is able to effectively treat as well as prevent plantar fasciitis by reducing the tensile stress in the plantar fascia.

I believe Mr. Bushby's product provides a solution to the long-standing problem, which is the need for a product to prevent damaging tensile stress in the plantar fascia while allowing the user to remain active in athletic activities.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are

punishable by fine or imprisonment or both under Section 1001 of the Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



David M. de Lemos, M.D.



Date

X. RELATED PROCEEDINGS APPENDIX

None